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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/306,111	05/06/1999	KENNETH JACOBS	01997,007000	3040

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EXAMINER
BRUSCA, JOHN S

ART UNIT	PAPER NUMBER
1631	20

DATE MAILED: 05/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No. 09/306,111	Applicant(s) WIDOM ET AL.	
	Examiner John S. Brusca	Art Unit 1631	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 14 May 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☒ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *see comments above*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☒ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: *none*.

   Claim(s) objected to: *none*.

   Claim(s) rejected: *1,5,8 and 14-19*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

John S. Brusca
Primary Examiner
Art Unit: 1631

Continuation of 2. NOTE: The applicant's arguments that the rejection of claims 1-5, 8, and 14-19 under 35 U.S.C. § 101 and 112, first paragraph is improper are not persuasive. The applicants state that a prima facie showing has not been made to support the rejection. However, the utility guidelines published 05 January 2001 state:

3. Any rejection based on lack of utility should include a detailed explanation why the claimed invention has no specific and substantial credible utility. Whenever possible, the examiner should provide documentary evidence regardless of publication date (e.g., scientific or technical journals, excerpts from treatises or books, or U.S. or foreign patents) to support the factual basis for the prima facie showing of no specific and substantial credible utility. If documentary evidence is not available, the examiner should specifically explain the scientific basis for his or her factual conclusions.

(a) Where the asserted utility is not specific or substantial, a prima facie showing must establish that it is more likely than not that a person of ordinary skill in the art would not consider that any utility asserted by the applicant would be specific and substantial. The prima facie showing must contain the following elements:

(1) An explanation that clearly sets forth the reasoning used in concluding that the asserted utility for the claimed invention is not both specific and substantial nor well-established;

(2) Support for factual findings relied upon in reaching this conclusion; and

(3) An evaluation of all relevant evidence of record, including utilities taught in the closest prior art.

(b) Where the asserted specific and substantial utility is not credible, a prima facie showing of no specific and substantial credible utility must establish that it is more likely than not that a person skilled in the art would not consider credible any specific and substantial utility asserted by the applicant for the claimed invention.

The prima facie showing must contain the following elements:

(1) An explanation that clearly sets forth the reasoning used in concluding that the asserted specific and substantial utility is not credible;

(2) Support for factual findings relied upon in reaching this conclusion; and

(3) An evaluation of all relevant evidence of record, including utilities taught in the closest prior art.

(c) Where no specific and substantial utility is disclosed or is well-established, a prima facie showing of no specific and substantial utility need only establish that applicant has not asserted a utility and that, on the record before the examiner, there is no known well-established utility.

In this instance, it is not possible to provide documentary evidence that the claimed polynucleotides do not encode polypeptides that are useful as a polypeptide with kanadaptin activity. This is because the claimed polynucleotides have not been characterized in the prior art as to the capabilities of the encoded polypeptides. For the scientific reasoning of record, it is maintained that it is not credible from the evidence of record that the claimed polynucleotides encode polypeptides that have kanadaptin activity. The applicants further state that the claimed polynucleotides could be used to further study the function of prior art proteins, but they fail to explain how this is not merely further research on the claimed polynucleotides. Further research on the claimed invention is not considered to be a substantial utility. Th applicants state their assertion that the claimed polynucleotides encode polypeptides with kanadaptin activity is sufficient to meet the requirements of 35 U.S.C. § 101, however any assertion of utility must be credible to one of skill in the art, and absent any evidence that the assertion is true the assertion cannot be credible to one of skill in the art. As stated in the Office action mailed 23 November 2001, similarity does not automatically equate with identical function. The applicants state that U.S. Patents have issued with claims drawn to polynucleotides that hybridize to a disclosed polynucleotide. However, it is the underlying utility of the disclosed polynucleotide that is in question here. Were a polynucleotide consisting of SEQ ID NO. 2 to have a patentable utility, there would ordinarily be patentable utility a least for polynucleotides that encoded the same polypeptide as encoded by SEQ ID NO:2. Were there a patentable utility to use SEQ ID NO:2 as a probe there would ordinarily be patentable utility for polynucleotides that hybridized to SEQ ID NO:2 under high stringency conditions. Here it is the underlying patentable utility of SEQ ID NO:2 that is in question. The applicants state that the term isolated is objected to, however there is no such objection of record. Claims 1-5, 8, and 14-19 are rejected under 35 U.S.C. § 112, first paragraph fo lack of written description. The applicants argued in the amendment filed 4 January 2002 that because the claims are drawn to isolated polynucleotides the claims cannot encompass undescribed polynucleotides such as genomic sequence polynucleotides. This argument was not found persuasive for reasons of record in the Office action mailed 26 February 2002. The applicants state that the claims have been amended to recite "consisting essentially of", however no such amendment has been made. "Consisting essentially of" is considere to be open language equivalent to "comprising" unless otherwise defined by the applicants in the specification (see the Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, 1st paragraph, "Written Description " Requirement published 5 January 2001 in the Federal Register, Vol. 66, No.4. It is further noted that claim 1 in the proposed amendment continues to recite "An isolated polynucleotide comprising" which is considered to be open language reading on undescribed polynucleotides.